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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, Defendant.	Case No. 2:20-cv-374 (SMJ) December 28, 2020 Without Oral Argument

PARTIAL MOTION TO DISMISS

The Secretary hereby renews his motion to dismiss two claims under Federal Rule of Civil Procedure 12(b)(6). The Secretary's initial motion was denied by the district court for the District of Columbia, without prejudice to refiling after transfer to this Court.

BACKGROUND

A. Medicare and its Claim Appeal Process

Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, which is administered on behalf of the Secretary of Health and Human Services by the Centers for Medicare & Medicaid Services (CMS). Part A of the Medicare statute "covers medical services furnished by hospitals and other institutional care providers." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011) (citing 42 U.S.C. §§ 1395c to 1395i-5). Medicare Part B "is an optional supplemental insurance program that pays for medical items and services not covered by Part A, including outpatient physician services" and "durable medical equipment," among other things. *Id.* (citing 42 U.S.C. §§ 1395j to 1395w-4). This case presents the question of whether a certain continuous glucose monitor is durable medical equipment under the statute and regulations. *See* 42 U.S.C. § 1395x(n); 42 C.F.R. § 414.202.

Medicare beneficiaries submit claims for coverage of durable medical equipment to administrative contractors (formerly known as fiscal intermediaries) hired by the agency to make initial coverage determinations. 42 C.F.R. § 405.920 *et seq.*; *see Porzecanski v. Azar*, 316 F. Supp. 3d 11, 15 (D.D.C. 2018); 42 U.S.C. § 1395ff(a)(1) (authorizing the Secretary to "promulgate regulations and make initial determinations with respect to benefits under . . . part B of this subchapter").

"If the beneficiary disagrees with the contractor's initial determination," she "may request a 'redetermination' by the same contractor." *Porzecanski*, 316 F. Supp. 3d at 15 (citing 42 C.F.R. § 405.940); *see* 42 U.S.C. § 1395ff(a)(3). If the beneficiary remains unsatisfied, she may request "reconsideration" of her claim by another contractor, known as a "qualified independent contractor." 42 C.F.R. § 405.960 *et seq.*; *see* 42 U.S.C. § 1395ff(c).

A dissatisfied beneficiary may then request a hearing before an administrative law judge (ALJ), 42 C.F.R. § 405.1000(a), if she satisfies the amount-in-controversy requirement. 42 U.S.C. § 1395ff(b)(1)(E); 84 Fed. Reg. at 53,445 (minimum amount in controversy for ALJ review now $170). After the ALJ issues a decision, the beneficiary or CMS may seek review by the Medicare Appeals Council, 42 C.F.R. § 405.1100 *et seq.*; *see id.* § 405.1102, which makes the final decision for the Secretary, *id.* § 405.1130. If the beneficiary is not satisfied with the decision of the Medicare Appeals Council, she may then seek judicial review, subject to another amount-in-controversy requirement. 42 U.S.C. § 1395ff(b)(1)(E); 84 Fed. Reg. at 53,445 (establishing $1,630 minimum amount in controversy for judicial review in 2019).

B. Factual Allegations

Jeremy Olsen is a Medicare beneficiary who resides in Chattaroy, WA. Corrected Compl. Caption & ¶ 4, ECF No. 3-1 (hereafter "Compl."). In July 2018,

a Medicare administrative contractor denied three claims totaling $2,444 for supplies related to Mr. Olsen's continuous glucose monitor. *Id.* ¶¶ 53–54. That denial was upheld on redetermination and reconsideration, but reversed by an administrative law judge. *Id.* ¶¶ 55–57. CMS then sought review by the Medicare Appeals Council, which denied coverage on July 23, 2019. *Id.* ¶¶ 58–59. After receiving two extensions, Mr. Olsen filed a timely suit for judicial review of the Secretary's decision. *Id.* ¶ 60.

LEGAL STANDARD

A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Thus, to survive a motion to dismiss for "failure to state a claim upon which relief may be granted," Fed. R. Civ. P. 12(b)(6), the complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A "claim has facial plausibility when the plaintiff pleads factual content that allows the [C]ourt to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). Although the Court must accept the facts pleaded as true, legal allegations devoid of factual support are not entitled to this presumption. *See, e.g., Doe v. Holy See*, 557 F.3d 1066, 1073 (9th Cir. 2009).

ARGUMENT

A. Two claims must be dismissed under Rule 12(b)(6).

The complaint alleges six claims, two of which must be dismissed for failure to state a claim on which relief can be granted.

First, the Court must dismiss the claim brought under 5 U.S.C. § 706(1), which empowers district courts to "compel agency action unlawfully withheld or unreasonably delayed." *See* Compl. ¶¶ 61–63. Mr. Olsen does not allege that the Secretary has failed to take some required action: there is no dispute that the Secretary adjudicated his claim for benefits. *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (explaining that "a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*" (emphasis in original)). Rather, Mr. Olsen argues that the Secretary's adjudication was substantively invalid, that his claim for benefits was denied when it should have been approved. That simply is not a § 706(1) claim. *See Montanans For Multiple Use v. Barbouletos*, 568 F.3d 225, 227 (D.C. Cir. 2009) (upholding the dismissal of "a § 706 failure-to-act claim" where the complaint did not "identify a legally required, discrete act that the [agency] has failed to perform"); *Hells Canyon Preservation Council v. U.S. Forest Service*, 593 F.3d 923, 932 (9th Cir. 2010) (discussing the scope of § 706(1)). Section 706(1) provides for "judicial review of agency inaction,"

Norton, 542 U.S. at 61, not cases in which plaintiffs challenge the substantive validity of agency action. Mr. Olsen can attempt to show that the Secretary's decision was "arbitrary, capricious, . . . or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), "short of statutory right," *id.* § 706(2)(C), or "unsupported by substantial evidence," *id.* § 706(2)(E). But he cannot bring a failure-to-act case when the Secretary has actually adjudicated his claim for benefits. Mr. Olsen's claim under § 706(1) must be dismissed.

Second, the Court should dismiss the claim alleging a violation of 5 U.S.C. § 706(2)(D), which grants district courts the authority to hold unlawful agency action that is taken "without observance of procedure required by law." Compl. ¶¶ 70–72. Mr. Olsen has sought "judicial review of the Secretary's final decision" denying his claim. 42 U.S.C. § 1395ff(b)(1)(A). There is no allegation that the Secretary's decision itself was procedurally invalid. The complaint makes reference to 1) a CMS Ruling, which is an agency document that binds the Medicare Appeals Council, but not this Court, to its views, *see* 42 C.F.R. §§ 401.108, 405.1063(b); 2) a local coverage determination (LCD), which is a decision by a Medicare administrative contractor "respecting whether or not a particular item or service is covered" by that contractor, 42 U.S.C. § 1395ff(f)(2)(B), but does not bind this Court or higher levels of the administrative appeals process, *see id.* § 1395ff(c)(3)(B)(ii)(II); and 3) a policy

article, which is a guidance document with no binding weight at any level of the administrative appeal process, *see* 85 Fed. Reg. 19,230, 19,266 (Apr. 6, 2020) (explaining that Policy "Articles are often published alongside LCDs and contain coding or other guidelines that complement an LCD").

This Court has no jurisdiction to review the policy article, which is not final agency action (because it is not binding at any level), and has nothing to do with Mr. Olsen's claim here. *See, e.g.*, *Jordan Hosp. v. Leavitt*, 571 F. Supp. 2d 108, 113–14 (D.D.C. 2008) (discussing review of final agency action under the Medicare statute). Judicial review of local coverage determinations is available through a special statutory mechanism that Mr. Olsen did not invoke. 42 U.S.C. § 1395ff(f)(2)(A)(iv) (providing for judicial review of the validity of a local coverage determination after a separate administrative review process). This Court has no jurisdiction to review a local coverage determination outside of that process. *Vertos Med., Inc. v. Novitas Solutions, Inc.*, 2012 WL 5943542, at *3–*4 (S.D. Tex. Nov. 27, 2012); *see Porzecanski v. Azar*, 943 F.3d 472, 482 (D.C. Cir. 2019) ("[T]o the extent [a beneficiary] desires broader relief outside the case-by-case adjudicatory model, he has a clear administrative path to challenge an LCD . . . , *see* 42 U.S.C. § 1395ff(f)(2)(A), . . . subject . . . to *judicial review after final agency action*." (citing 42 U.S.C. § 1395ff(f)(2)(A)(iv) (emphasis added)); *California Clinical Lab. Ass'n v. Sec'y of Health & Human Servs.*, 104 F. Supp. 3d

66, 72 (D.D.C. 2015). Mr. Olsen, moreover, has not alleged that the local coverage determination played any meaningful role in the ultimate denial of his claim for benefits.

As for the CMS Ruling, this Court can review the *substantive* validity of its interpretation of the Medicare statute and regulations to the extent that it was the basis for "the Secretary's final decision" denying Mr. Olsen's claim, which is the final agency action at issue here. 42 U.S.C. § 1395ff(b)(1)(A). As to any *procedural* infirmity, if Mr. Olsen's allegation is that a) the CMS Ruling was invalidly issued and b) the Secretary's final decision was tainted by his reliance on a procedurally invalid Ruling, then this Court could consider that argument in reviewing the Secretary's decision itself. But that argument would not lead to the direct invalidation of the CMS Ruling (which is not before this Court), nor the principal relief that Mr. Olsen appears to be seeking: an order that the Secretary approve his claim for benefits. If the Secretary's final decision improperly relied on a procedurally invalid CMS Ruling, then the remedy is a remand so that the Secretary can decide Mr. Olsen's claim without reference to the disputed Ruling. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014). If Mr. Olsen wishes to assert the claim that the Secretary's final decision was invalid because it relied on a procedurally infirm CMS Ruling, he should be given leave to amend his complaint to do so clearly, rather than leaving the Court and the

Secretary to guess. But from the face of the present complaint, it appears that he is seeking a substantive reversal of the Secretary's final decision, and so his claim alleging a procedural violation of 5 U.S.C. § 706(2)(D) must be dismissed.

CONCLUSION

This Court should dismiss Mr. Olsen's § 706(1) and § 706(2)(D) claims under Rule 12(b)(6).

Respectfully submitted,

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